

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

PADDOCK LABORATORIES, INC.,

Plaintiff,

v.

ETHYPHARM S.A., LUPIN LIMITED,
and LUPIN PHARMACEUTICALS, INC.,

Defendants.

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ELECTRONICALLY**

Civil Action No. 09-cv-03779 (GEB)(LHG)

**MEMORANDUM IN SUPPORT OF LUPIN LIMITED'S AND
LUPIN PHARMACEUTICALS, INC.'S MOTION TO
DISMISS THE AMENDED COMPLAINT**

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Lupin Limited and Lupin Pharmaceuticals, Inc. (“LPI”) submit this memorandum in support of their motion to dismiss the Amended Complaint. Dismissal is proper because neither Lupin Limited nor LPI is a proper defendant in this action, there is a lack of personal jurisdiction over Lupin Limited under FED. R. CIV. P. 12(b)(2), and there was insufficient service of process on Lupin Limited under FED. R. CIV. P. 12(b)(5).

I. SUMMARY OF THE ARGUMENT

Paddock Laboratories, Inc. (“Paddock”) filed the present action under a provision of the Hatch-Waxman Act seeking a declaratory judgment that the proposed generic product described in Paddock’s Abbreviated New Drug Application (“ANDA”) would not infringe U.S. Patent 7,101,574 (“the ’574 patent”) and/or that the ’574 patent is invalid. *See* Amended Complaint ¶¶ 46, 54, 58 and 59; 21 U.S.C. § 355(j)(5)(C)(i)(II).

The statutory provision relied upon by Paddock in support of this action, however, provides that an ANDA applicant, such as Paddock, may bring a civil action (*e.g.*, a declaratory judgment action) “against the owner [of the patent] or [New Drug Application] holder.” This provision further requires that any such action “shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.” 21 U.S.C. § 355(j)(5)(C)(i)(II).

Neither Lupin Limited nor LPI is the owner of the ’574 patent, nor are they the holder of the relevant New Drug Application (“NDA”). Moreover, Lupin Limited does not have a principal place of business, or a regular and established place of business, in this judicial district. In addition, service of the Amended Complaint on Lupin Limited was improper, and thus ineffective, under the Federal Rules of Civil Procedure.

For these reasons, Lupin Limited and LPI respectfully request dismissal of the Amended Complaint.

II. RECITATION OF THE RELEVANT FACTS

In an effort to obtain approval to market generic versions of 43 mg and 130 mg Antara® capsules in the United States, Paddock filed ANDA No. 91-362 (“Paddock’s ANDA”) with the FDA. *See* Amended Complaint ¶ 38. Paddock subsequently brought this declaratory judgment action under the Hatch-Waxman Act (“the Act”) seeking a determination by this Court that the ’574 patent is invalid and/or would not be infringed by the generic capsules described in Paddock’s ANDA. *See* Amended Complaint ¶¶ 44, 46.

The provision of the Act relied on by Paddock as supporting this declaratory judgment action states that an ANDA applicant may bring a civil action (*e.g.*, a declaratory judgment action) “against the owner [of the patent] or [New Drug Application] holder,” but that any such action “shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.” 21 U.S.C. § 355(j)(5)(C)(i)(II).

Neither Lupin Limited nor LPI is an owner of the ’574 patent, nor is either the holder of the New Drug Application (“NDA”) for Antara®.

The ’574 patent, entitled “Pharmaceutical Composition Comprising Fenofibrate and the Preparation Method,” issued on September 5, 2006. *See* Declaration of Kate M. Lesciotto at Exhibit A (*hereinafter* “Lesciotto Decl., Exh. ____.”) The ’574 patent is listed in the FDA-publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the “Orange Book”) as relating to Antara® capsules. *See* Amended Complaint ¶ 24. The first page of this patent identifies “Laboratoires des Produits Ethiques Ethypharm” as the sole assignee. *See* Lesciotto Decl., Exh. A. However, the U.S. Patent and Trademark Office (“USPTO”) assignment database currently identifies Ethypharm, one of the other named defendants in this action, as the sole owner of the ’574 patent. *Id.* at Exh. B. FDA records indicate that the current holder of the NDA for Antara® is Lupin Atlantis. *Id.* at Exh. C.

Further, neither Lupin Limited nor LPI have a principal place of business, nor a regular and established place of business, within this judicial district. Lupin Limited is a corporation organized under the laws of the Republic of India with a principal place of business in Mumbai, India. *See* Declaration of William Gileza at ¶ 9 (*hereinafter* “Gileza Decl., ¶ ____.”) LPI is a Virginia corporation, with a principal place of business in Baltimore, Maryland. *Id.* at ¶ 5.

Unable to locate Lupin Limited within this judicial district, Paddock attempted to effect service of the Amended Complaint on Lupin Limited by personally serving Ms. Vinita Gupta. Ms. Gupta is the Group President & CEO of LPI, a wholly-owned subsidiary of Lupin Limited. *Id.* at ¶ 4. Ms. Gupta is not an employee of Lupin Limited, does not have any executive or management responsibilities at Lupin Limited, and is not authorized to accept service on behalf of Lupin Limited, although she does sit on its Board of Directors as a non-executive, outside director. *Id.* at ¶¶ 6, 7, and 8.

That Lupin Limited could not be found by Paddock within this judicial district is not surprising. Lupin Limited has no offices, manufacturing facilities, mailing addresses, telephone numbers, or employees in the District of New Jersey. *Id.* at ¶ 10. Lupin Limited neither owns nor rents real or personal property in the District of New Jersey. *Id.* at ¶ 11. Nor does Lupin Limited maintain any bank accounts in the District of New Jersey. *Id.* at ¶ 12. Lupin Limited has never solicited and does not solicit nor sell any products or services in the District of New Jersey, and does not conduct any business in the District of New Jersey. *Id.* at ¶ 13. Lupin Limited is not incorporated in, licensed, authorized, or registered to do business in the District of New Jersey. *Id.* at ¶ 14. Neither has Lupin Limited appointed any agent or public official for service of process in the District of New Jersey. *Id.* at ¶ 15.

III. ARGUMENT

A. LUPIN LIMITED AND LPI ARE NOT PROPER DEFENDANTS IN THIS ACTION

The statutory provision relied upon by Paddock in support of this action provides that an ANDA applicant, such as Paddock, may bring a civil action (*e.g.*, a declaratory judgment action) “against the owner [of the patent] or [NDA] holder.” 21 U.S.C. § 355(j)(5)(C)(i)(II).

The facts set forth in Section II *supra* establish that Lupin Limited and LPI are neither an owner of the ’574 patent nor the NDA holder for Antara®. Moreover, neither has a principal place of business, nor a regular and established place of business, within this judicial district. Pursuant to Section 355(j)(5)(C)(i)(II), Paddock instituted this action against incorrect legal entities. For these reasons, the Amended Complaint should be dismissed as against Lupin Limited and LPI.

B. LUPIN LIMITED IS NOT SUBJECT TO PERSONAL JURISDICTION IN THE DISTRICT OF NEW JERSEY

1. Legal Standards

A corporation must have sufficient minimum contacts with a forum to properly exercise personal jurisdiction over it. The plaintiff has the burden of establishing a factual basis for the exercise of personal jurisdiction over the defendant. *Provident Nat’l Bank v. Cal. Fed. Savings & Loan Ass’n*, 819 F.2d 434, 437 (3rd Cir. 1987). Moreover, “the plaintiff is required to sustain its burden through sworn affidavits or other competent evidence; at no point may a plaintiff rely on the pleadings alone in order to withstand an *in personam* jurisdictional attack.” *Amberson Holdings LLC v. Westside Story Newspaper*, 110 F. Supp. 2d 332, 335 (D.N.J. 2000).

In addressing personal jurisdiction, a federal court must engage in a two-step inquiry. First, the court must look to the state’s long-arm statute to determine whether it permits the exercise of personal jurisdiction. Second, the Due Process Clause of the Constitution is applied.

Imo Indus. v. Kiekert AG, 155 F.3d 254, 259 (3rd Cir. 1998). In New Jersey, these two steps collapse into one because the New Jersey long-arm statute has been interpreted to extend jurisdiction over non-resident defendants to the fullest extent allowed by the United States Constitution. *Id.*

As an initial matter, the plaintiff must demonstrate that the defendant has “purposefully avail[ed] itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws.” *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 475 (1985) (quoting *Hanson v. Denckla*, 357 U.S. 235, 253 (1958)). If it is able to do so, the plaintiff must then establish that “either that particular cause of action sued upon arose from the defendant’s activities within the forum state (“specific jurisdiction”) or that the defendant has “continuous and systematic” contacts with the forum state (“general jurisdiction”).” *Provident Nat’l Bank*, 819 F.2d at 437 (citing *Helicopteros Nacionales de Columbia S.A. v. Hall*, 466 U.S. 408, 414, 416 (1984)).

Lupin Limited does not have the “minimum contacts” necessary to be subjected to personal jurisdiction in this Court for it does not maintain “continuous and systematic” contacts with this district, nor can it be said that it is “doing business” within this district.

2. Personal Jurisdiction Over Lupin Limited Is Improper

Specific jurisdiction over a foreign defendant may only be established when that defendant “has ‘purposefully directed’ [its] activities at a resident of the forum and the injury arises from or is related to those activities.” *Gen. Elec. Co. v. Deutz AG*, 270 F.3d 144, 150 (3rd Cir. 2001). Stated another way, “[q]uestions of specific jurisdiction are properly tied to the particular claims asserted.” *Id.* It is clear in this case that Lupin Limited has neither purposefully directed any activity toward a resident of this judicial district, nor does any alleged

injury to Paddock arise from or relate to any of Lupin Limited's activity within this judicial district.

Paddock is a Minnesota corporation, and has not alleged that it resides within this judicial district (and thus cannot aver that it suffered any injury within this district), nor identified any specific injury that has or would arise due to Lupin Limited's activity within this district. *See, e.g.,* Amended Complaint ¶ 9. Nor can Paddock do so, as Lupin Limited has no presence within this judicial district. As stated previously, Lupin Limited is a corporation organized under the laws of the Republic of India, with a place of business in Mumbai, India. Lupin Limited has no presence within this judicial district: no offices, manufacturing facilities, mailing addresses, telephone numbers, or employees are here; it neither owns nor rents real or personal property here; it does not maintain any bank accounts in this district; it has never solicited and does not solicit nor sell any products or services here; does not conduct any business here; is not incorporated in, licensed, authorized, or registered to do business in this district, and has not appointed any agent or public official for service of process here. *See* Section II, *supra*.

These facts do not support specific or general jurisdiction over Lupin Limited, as the latter has no presence (or activity) within this judicial district, and has no continuous and systematic contacts with this district. *See Walburn v. Rovema Packaging Machines, L.P.*, Civil Action No. 07-3692, 2008 WL 852443, at *5 (D.N.J. Mar. 28, 2008) (holding that there was no general personal jurisdiction over a non-resident corporation when it did not advertise, own property, or maintain offices in New Jersey).

Moreover, as Lupin Limited is neither the owner of the '574 patent nor the NDA holder for Antara®, there appears to be no reasonable basis for any assertion by Paddock that Lupin Limited has caused Paddock any injury, let alone an injury due to (non-existent) activities by Lupin Limited, within this judicial district.

For at least the foregoing reasons, the Amended Complaint should be dismissed as against Lupin Limited for lack of personal jurisdiction.

C. SERVICE OF PROCESS ON LUPIN LIMITED WAS INEFFECTIVE

Service of a copy of the summons and complaint upon a foreign corporation is guided by FED. R. CIV. P. 4(h), which states that service on a foreign corporation may be accomplished “(A) in the manner prescribed by Rule 4(e)(1) for serving an individual; or (B) by delivering a copy of the summons and of the complaint to an officer, a managing or general agent, or any other agent authorized by appointment or by law to receive service of process.” FED. R. CIV. P. 4(h)(1). Rule 4(e)(1) indicates that service upon an individual may be accomplished by “following state law for serving a summons.” FED. R. CIV. P. 4(e)(1).

Even with the expansion of FED. R. CIV. P. 4(h)(1)(A) to include appropriate state methods of service of process, Paddock failed to effect proper service on Lupin Limited. New Jersey law provides that service shall be made upon a corporation by serving a copy of the summons and complaint “on any officer, director, trustee, or managing or general agent, or any person *authorized by appointment or by law to receive service of process on behalf of the corporation.*” N.J. CT. R. 4:4-4(a)(6).

Paddock attempted to effect service on Lupin Limited by personally serving the Amended Complaint on Ms. Gupta. Ms. Gupta is the Group President & CEO of LPI, a wholly-owned subsidiary of Lupin Limited. *See* Gileza Decl., ¶ 4. Ms. Gupta is not an employee of Lupin Limited, does not have any executive or management responsibilities at Lupin Limited, and is not authorized to accept service on behalf of Lupin Limited, although she does sit on its Board of Directors as a non-executive, outside director. *Id.* at ¶¶ 6, 7, and 8.

These facts demonstrate that Ms. Gupta is does not have any executive, managerial or other employment relationship with Lupin Limited. Moreover, she is not authorized to receive

service of process on behalf of Lupin Limited. *Id.* at ¶ 8. Under FED. R. CIV. P. 4(h)(1)(A) and New Jersey state law, or under FED. R. CIV. P. 4(h)(1)(B) which identifies officers, managing or general agents, personal service upon Ms. Gupta—a non-employee, non-manager, and non-executive director of Lupin Limited— did not effect service on Lupin Limited. *See Gottlieb v. Sandia Am. Corp.*, 452 F.2d 510, 513 (3rd Cir. 1971) (“The determination whether an individual is “a managing or general agent” depends on a factual analysis of that person’s authority within the organization. * * * He should be “a responsible party in charge of any substantial phase” of the corporation’s activity. In brief, it is reasonable to expect that such an agent will have broad executive responsibilities and that his relationship will reflect a degree of continuity.”) (internal citations omitted).

IV. CONCLUSION

For the reasons set forth herein, Lupin Limited and LPI respectfully request that the Amended Complaint be dismissed because neither Lupin Limited nor LPI is a proper defendant in this action, there is a lack of personal jurisdiction over Lupin Limited under FED. R. CIV. P. 12(b)(2), and there was insufficient service of process on Lupin Limited under FED. R. CIV. P. 12(b)(5).

Respectfully submitted,

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